RE: Docket NO. 98N-1265

janet flanders travel inc.
662 the seasoned traveler

July 19, 1999

Dear FDA, Congressmen Leahy, Jeffords and Sanders:

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice, (in some cases, from any provider), and infringes on the rights of compounding pharmacies to serve the public's needs.

I live in Norwich, VT. To get natural hormones, I must go out of state. I want natural hormones because they are identical to what my body once produced. Premarin is from abused horses; for ethical reasons it should be banned, since plant estrogens are available (but not patentable), but more importantly, it is horse estrogen, not human. The patented progesterones cause many side effects and are also not identical to human. The FDA requirements that massive sums must be spent for testing means that pharmaceutical companies keep devising synthetic alternatives to natural and available versions. Without a patent, they cannot recoup their huge costs. The FDA forces this pattern to continue.

The FDA should review abailable data (especially that done by European governments who have a consumer driven system of drug approval) and not have to re-do studies already completed. Our system is based on greed instead of need.

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I get my hormones from Women's International Pharmacy in Madison, Wisconsin. Seven years ago, I could not get them at Dartmouth Hitchcock Medical Center, which is affilliated with Dartmouth Medical School, both 2 miles from my home. This legislation would penalize the pharmacies that have been supporting consumer need over corporate greed. It is wrong! The FDA approves drugs that KILL people every day, but tries to prohibit those that do good but little or no harm, and prevents consumers from getting good information: imagine, forcing companies to produce supplements without any information at all. The public does not trust the FDA. Be brave, and you can change the publics view of the FDA.

Sincerely yours,

Janet Flanders

Janet Flanders

ENC: copy of Health & Healing special supplement

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SPECIAL SUPPLEMENT

The FDA approves drugs that kill people everyday but trys to keep the people from knowing anything about natural supplements. The public does not trust the FDA!

Julian Whitaker, M.D.
Health & Healing®
TOMORROW'S MEDICINE TODAY

Special Supplement to *Julian Whitaker, M.D. Health & Healing*
July 1999

A New Birth of Freedom for Supplement Health Claims

The United States Capitol served as the stage for this event.

May 25, 1999, was a bluebird spring day. I was on the lawn in front of the nation's Capitol, along with Senators Orrin Hatch (R-Utah) and Tom Harkin (D-Iowa) and Congressman Peter DiFazio (D-Oregon). I had called a press conference to announce that I and three others had petitioned the Food and Drug Administration (FDA) for "permission" to use truthful health claims on the labels of nutritional supplements. But before I get into our specific requests, you need to know why I was there at that time.

This Battle Started Eight Years Ago

For over 25 years the FDA has prevented nutritional supplement manufacturers from telling you about the health benefits of their products. Incredibly, billions of bottles of supplements have been sold ***with no information at all*** on the labels explaining what the product is supposed to do. Because the label is "off limits" as a source of information about nutritional and herbal products, consumers must turn to books, newsletters, and the Internet. But that is going to change—and change fast.

In January of this year, the Circuit Court of Appeals ruled that the FDA's 25-year-old regime of censorship of the nutritional supplement industry was both illegal and a violation of the constitutional guarantee of free speech and press. The court ordered the FDA to allow health claims that had been submitted eight years ago by Durk Pearson and Sandy Shaw, long-time crusaders for freedom of speech on nutritional supplements, and which the FDA had categorically denied.

Now We're Filing Four Claims

At the press conference we announced the addition of four more claims that the FDA must act upon in the next six months. According to Jonathan Emord, the attorney who brilliantly and successfully argued this case before the courts, this will be the first real test of the FDA's willingness to adhere to the Court's decision—and act in the interests of confused consumers.

Let's take a look at the four specific claims we filed and how they might affect your health.

Julian Whitaker, pictured with Sen. Harkin, welcomed members of the press and made his opening remarks.

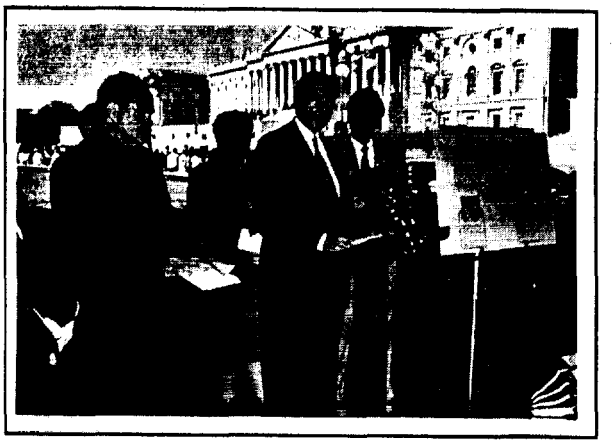
Claim 1. ***Supplementary intake of folic acid, vitamin B6, and vitamin B12 may reduce the risk of cardiovascular disease.*** An estimated 30% of all heart attacks could be prevented with supplemental folic acid, vitamin B6 and vitamin B12. Research in support of this statistic has existed for well over a decade. Because of the FDA's censorship of supplement manufacturers, many families who have lost a loved one to heart disease may understandably blame the FDA for their tragedy.

Claim 2. ***Daily use of saw palmetto extract may improve urine flow and reduce nocturia and voiding urgency associated with mild benign prostatic hyperplasia (BPH).*** BPH is such a common problem among men as they age that Representative DeFazio said in his statement to the press that this is the claim that might get the most attention from his colleagues in Congress, as they are "sitting around on their enlarged prostates." Studies show that supplemental saw palmetto results in significant improvements in the majority of men suffering with BPH.

Claim 3. ***Psyllium seed husks used as a dietary fiber supplement may reduce the risk of heart disease.*** Psyllium fiber has been shown to reduce total cholesterol and LDL cholesterol levels. Elevated levels of both affect 60% of American adults and are significant markers of heart disease.

Claim 4. ***Supplemental vitamin E may help prevent cardiovascular disease.*** The therapeutic potential and health benefits of vitamin E have been recognized for over 50 years, and the body of supporting scientific research continues to grow. In one study of 2,000 people with heart disease, those taking supplemental vitamin E experienced a 75% reduction in heart attack incidence.

With the distinguished panel standing behind him, Sen. Harkin urged the FDA to act in a prompt and timely manner.



Sen. Orrin Hatch chided the FDA for acting as the "nation's nanny."

FDA Censorship Has Likely Harmed Many Americans

Folks, we need to remember that this issue directly affects people's lives. When a government agency is in violation of statutory law as well as the Constitution, the result is almost always disastrous for certain segments of the population. The FDA's censorship of vital information on the specific benefits of nutritional supplements is nothing short of perverse, and many years of suppression have caused immeasurable suffering, countless deaths, and billions of dollars in preventable medical costs. Let me give you one graphic example.

As long ago as 1992, there was substantial scientific evidence to show that 400 mcg of folic acid per day could reduce the risk of neural tube birth defects, such as ***spina bifida*** and ***hydrocephalus***, by as much as 50%. In fact, the Center for Disease Control and Prevention (CDC) published the following recommendation that year:

> "All women of childbearing age in the United States who are capable of becoming pregnant should consume .4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with ***spina bifida*** or other neural tube defects."

It Took Fours Years for Folic Acid Claims

Despite this recommendation, the FDA prohibited vitamin manufacturers from printing this claim on bottles of supplements containing folic acid. The agency finally reversed itself in 1996, relenting only under growing political pressure from Senator Orrin Hatch and Congressman Bill Richardson. However, during those four years, the FDA's unreasonable refusal to permit this folic acid claim where it could do the most good contributed to an estimated 10,000 neural tube birth defects! Imagine, 10,000 children and their families suffer the consequences of these tragic birth defects—which could have been prevented, had the FDA acted in a timely manner.

It gets even worse. The FDA actually squelched efforts of a state agency to improve the health of its citizens. The Texas Department of Public Health recognized in 1992 that in Cameron County, an impoverished rural county in southern Texas, the incidence of ***spina bifida*** and neural tube defects was quite high. They put together a program to disseminate information on the prevention of these birth defects and to supply folic acid to women at risk. Incredibly, the FDA intervened, and this very important program was delayed for four years.

Sen. Hatch Urged the FDA to Act Quickly

I was honored by the support and presence at the press conference of Senator Hatch and Senator Harkin. These two senators, Republican and Democrat respectively, have consistently supported freedom of speech and access to alternative health information and therapies.

In his statement to the press, Senator Hatch encouraged the FDA to act quickly on these petitions and not drag them through a bureaucratic maze. "I urge the agency not to fumble the ball by reverting to the obstructionist tactics the courts, consumers, and the Congress have squarely rejected. The public has come to expect more of its government."

Julian Whitaker spoke with Sen. Tom Harkin and Rep. Peter DeFazio before the press conference.

Sen. Harkin Reminded the FDA of Its Mission

Senator Harkin echoed these sentiments. "The Court of Appeals decision on January 15th was an important victory for consumers' access to truthful and useful information. Now the FDA has the opportunity to show their commitment for consumer information in reviewing the four claims being submitted for review today. I join you in calling on the FDA to review those claims promptly and fairly. And 'promptly' does not mean a year or two, and 'fairly' does not mean entering it with a bias to say no. The FDA's mission is to promote the public health. With these petitions you are giving them a chance to do their job. We'll all be watching very closely."

Other Speakers Called for Responsible FDA Action

Representative DeFazio implored fairness on the part of the FDA. "We are here today to begin to turn the tide and say we are going to provide useful information. The FDA should go back and do what it's supposed to do, which is regulate in the public interest—not in the interest of some certain special interest."

Other speakers continued to give the FDA a hammering. Commenting on the petitions filed that day, Jonathan Emord stated, "For the sake of health care consumers and the rule of law, we can only hope that the FDA will do its duty and approve all four of the well-documented health claims presented today."

Nona Wegner spoke on behalf of the Seniors Coalition, a nonprofit organization that represents the interests and concerns of three million American senior citizens. She stated, "The January Court of Appeals ruling curtails

the government's role in making decisions for consumers, and that is a good thing. Seniors especially will derive tremendous benefits from the nutritional information we now expect to appear on the labels of nutritional supplements."

The Public Needs Accurate Information

Harry G. Preuss, MD, Professor of Medicine at Georgetown University Medical Center and a member of the Council for the Office of Alternative Medicine, gave a medical perspective of the situation. "...the public should be given proper information concerning the potential benefits of these nutraceuticals. There are other natural elements which could fall into this classification. Are there unforeseen possibilities for adverse reactions with long-term use? There is always a possibility. However, because of their natural status and long-term use, this is far more unlikely than the majority of 'cutting edge' pharmaceuticals now on the drug store shelves."

You Have a Right to Truthful Information on Nutritional Supplements

The impunity with which governments can transgress human freedoms is precisely why we have a constitutional government. The Bill of Rights was written not to protect you from dishonest nutritional supplement retailers, but to protect you from the forces of government. The first amendment to the Constitution says that government shall make no law to abridge freedom of speech. Yet the FDA instituted regulations that completely shut down speech on the value of nutritional supplements. Consequently, many intelligent people in our society still believe the nonsense that you can get all the nutrients you need for optimal health from diet alone. This is not to say that diet is an unimportant factor in health, but that the truth about the power of nutritional supplements has been rigidly and severely censored by the Food and Drug Administration.

Law Applies to Government Agencies, Too

When individuals in the private sector break the law and violate others' constitutional rights, they are punished. When individuals cloaked in the mantle of "government bureaucrat" break the law, violate others' constitutional rights and cause immeasurable damage in the lives of millions, they merely get some bad press. All of that is beginning to change, however, and I'll keep you informed as to the progress of our petition through the bureaucratic labyrinth of the FDA.

Here's How You Can Help

Folks, you can play a part in this, too. Please write to:

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

State that you are in favor of the FDA promptly approving claims filed for saw palmetto and the symptoms of benign prostatic hyperplasia; psyllium husk seeds and the risk of heart disease; folic acid, vitamin B6 and vitamin B12 and cardiovascular disease; and vitamin E and the risk of cardiovascular disease.

Please mail a copy of your letter to me, care of:

Health & Healing
Health Claims
7811 Montrose Road
Potomac, MD 20854

We're Winning, but We Must Stay Vigilant

The final court of appeals is the Supreme Court, but it is unlikely that the General Accounting Office will allow the FDA to spend taxpayers' money on yet another appeal to the courts, because their chances of having this decision reversed are so unlikely. This is why all of us are fighting to turn the FDA around completely, and at this junction we certainly are winning.

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